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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/030,452 | 01/10/2002 | Masayuki Yabuta | 58777.000002 | 5707 |

21967 7590 10/20/2004

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,452

Applicant(s)

YABUTA ET AL.

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-11 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper filed 25 May 2004. Claims 1-2 have been canceled.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Maintained Objections and Rejections

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yabuta *et al.* (US 5,670,340). The present claims are directed to a method of producing proteins in a culture medium or broth that is supplemented with any one of the amino acids histidine, methionine and glycine. Yabuta *et al.* teaches a process for the production of a protein (including atrial natriuretic peptide) comprising culturing E. coli host cells transformed with a plasmid capable of expressing the protein (see claim 1, for example). The broth or media used in during the incubation or growth step of the host cell E. Coli comprises 2.0 g/L of L-methionine (see

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Example 3). Thus, both product and method are taught and the reference anticipates the claimed invention.

Applicant argues that Yabuta *et al.* do not disclose O-acetylserine or the method of reducing the formation of a byproduct polypeptide comprising O-acetylserine. Careful examination of the independent claims 9 and 10 reveals that the recitation of the invention only requires culturing transformed host cells in a medium comprising at least one histidine, methionine or glycine in an effective amount to reduce the formation of a byproduct polypeptide. The recitation of O-acetylserine is limited to the preamble of the claims or as the inherent end-point of the claimed method.

Applicant is reminded that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitation are able to stand alone. See *In re Hirao*, 535, F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Thus, because Yabuta *et al.* teach a method of producing proteins in a culture medium that is supplemented with any one of the amino acids histidine, methionine and glycine in the amount required to inherently reduce the formation of polypeptides comprising O-acetylserine, the reference anticipates the invention as claimed.

5. Claims 3-6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmerman *et al.* (US 5,169,772). The present claims are directed to a method of producing

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proteins in a culture medium or broth that is supplemented with any one of the amino acids histidine, methionine and glycine. Zimmerman *et al.* teach an E.coli growth medium that is supplemented with methionine, proline, histidine and thiamine. The growth medium is used in a method of protein production. Thus, both product and method are taught and the reference anticipates the claimed invention.

Applicant argues that Zimmerman *et al.* do not disclose O-acetylserine or the method of reducing the formation of a byproduct polypeptide comprising O-acetylserine. Careful examination of the independent claims 9 and 10 reveals that the recitation of the invention only requires culturing transformed host cells in a medium comprising at least one histidine, methionine or glycine in an effective amount to reduce the formation of a byproduct polypeptide. The recitation of O-acetylserine is limited to the preamble of the claims or as the inherent end-point of the claimed method.

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Thus, because Yabuta *et al.* teach a method of producing proteins in a culture medium that is supplemented with any one of the amino acids histidine, methionine and glycine in the amount required to inherently reduce the formation of polypeptides comprising O-acetylserine, the reference anticipates the invention as claimed.

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Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

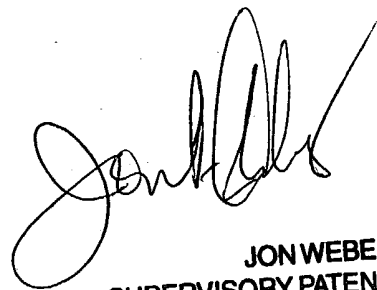
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
October 18, 2004

SKS

A handwritten signature in black ink, appearing to read 'Jon Weber', is written over a large, faint circular stamp.

**JON WEBER
SUPERVISORY PATENT EXAMINER**